



Legislative Reform of China's Healthcare Sector Targets Corruption: Implications for Multinational Companies

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In recent years, eliminating corruption in the healthcare industry has been a major focus of U.S. regulators. Since 2003, the U.S. Securities and Exchange Commission ("SEC") and Department of Justice ("DOJ") have brought over 30 enforcement actions against medical device and pharmaceutical companies under the U.S. Foreign Corrupt Practices Act ("FCPA").¹ China, which has figured in roughly a quarter of these cases, has responded in kind, revamping its own anti-bribery laws and initiating numerous investigations into the activities of domestic and international healthcare companies operating within its territory. Until recently, multinational healthcare companies operating in this challenging but growing market could afford to concentrate their compliance efforts on U.S., and, since the entry into force of the U.K. Bribery act in 2010, U.K. regulatory risks. Chinese regulators' proactive stance, as reflected by the announcement of their own industry sweeps of the pharmaceutical and medical device industries² and the seemingly endless succession of enforcement headlines that has followed, means that multinationals must now also focus on compliance with domestic law. This heightened focus on combatting corruption in the healthcare industry is clearly reflected in the recent adoption of several anti-bribery measures: Circulars 50,³ 163⁴ and 49.⁵

I. CIRCULARS 50 AND 163: A BIGGER, BADDER BLACKLIST

Effective March 1, 2014, Circular 50 updates existing rules for blacklisting healthcare companies engaged in bribery of state healthcare institutions and medical personnel, which had been in effect since January 2007,⁶ and expands the scope of activity subject to sanctions. Under the previous rules, healthcare companies and individual service providers who were convicted of commercial bribery by a Chinese court, investigated and sanctioned by Communist Party disciplinary authorities or subject to administrative penalties such as those issued by China's State Food and Drug Administration were subject to blacklisting.⁷ Provincial medical institutions were prohibited from purchasing pharmaceuticals, medical equipment and disposable medical products from such "blacklisted" companies for two years. Circular 50 extends blacklisting to situations in which (i) the defendant in a bribery prosecution is exonerated in court and (ii) the alleged crime is "minor" and the regulatory authority declines to pursue criminal charges.

In short, Circular 50 now raises the possibility that companies and their employees will be blacklisted simply because they become the target of a bribery investigation, even in cases where they are found not guilty in court or a prosecutor fails to press charges.⁸

Circular 50 also provides the following enhancements to existing blacklisting regulations:

- New pre-blacklisting administrative procedures to contest regulatory decisions;⁹
- Additional requirements for purchase and distribution agreements between hospitals and healthcare companies, including disclosure of the identity of the relevant sales representative and inclusion of anti-commercial bribery provisions;¹⁰
- Clarifications regarding the geographic scope and duration of sanctions. For public hospitals and other state-funded medical institutions, in addition to the existing prohibition against purchasing



goods from blacklisted companies for two years in the province where the bribery occurred, the new regulations impose a penalty in the form of a deduction of points when competing for government contracts in other provinces. If a company is blacklisted two or more times within a five-year period, the violator will be prohibited from selling its products to any public or publicly-funded medical institution nationwide;¹¹ and

- Obligations for healthcare institutions and lower-level healthcare authorities to report improper payments.¹²

Supplementing Circular 50, Circular 163, which came into effect on February 26, 2014, provides additional guidance on blacklisting procedures, establishing an aggressive timeline for the reporting, investigation and debarring of violators in as few as 25 working days.¹³ Of significant practical importance to business operators, Circular 163 also provides a sample “Agreement on Integrity in the Sale and Purchase of Healthcare Products” including model anti-bribery provisions for incorporation into sales agreements.¹⁴ Circular 163 also details the forms of compensation that medical institutions and personnel are prohibited from accepting, such as:

- Kickbacks “in any name or form”;
- Donations and sponsorships linked to procurement decisions;
- Entertainment in any commercial entertainment establishment; and
- Cash, securities and other valuable gifts.¹⁵

II. CIRCULAR 49: THE “NINE PROHIBITIONS”

While Circulars 50 and 163 focus on the supply-side of bribery in the healthcare sector, Circular 49, effective December 26, 2013, targets the recipients of potential improper payments: Chinese hospitals and medical personnel. Through its “nine prohibitions,” Circular 49 seeks to prevent hospitals and healthcare professionals from engaging in the following commercial activities:

1. Linking physicians’ income to revenue generated from the sale of drugs or provision of healthcare services;
2. Paying commissions to physicians based on the value of drugs prescribed and health services rendered;
3. Charging additional fees or raising fee standards beyond the permitted national price cap for drugs or healthcare services;
4. Accepting improper donations from healthcare companies;
5. Participating in promotional activities or issuing illegal advertisements;
6. Compiling medical statistical data for commercial purposes;
7. The procurement, sale, and use of medical products through private channels;
8. Accepting commissions or kick-backs in any form or attending activities held in commercial entertainment venues that are organized or sponsored by healthcare companies; and
9. Accepting cash or valuable gifts from patients or their families.

As the National Health and Family Planning Commission (“NHFP”) has yet to issue implementing regulations for Circular 49, many key terms remain open to interpretation. For example, it is unclear whether the prohibition under Article 4 against accepting “improper donations from healthcare companies” would extend to a healthcare professional’s receipt of a corporate sponsorship to attend a bona fide



medical education program, or even the provision of an educational grant to a third party under certain circumstances.¹⁶ Similarly, the term “promotional activities” in Article 5 is undefined, raising doubts about the types of activities and events that are covered, such as bona fide speaking engagements, providing compensation for the time and effort associated with which has long been a common practice in the industry.¹⁷

Such ambiguities among the Nine Prohibitions notwithstanding, Chinese healthcare professionals must comply with Circular 49 or face a range of disciplinary actions, from a simple warning to the suspension or cancellation of a medical license.

III. IMPLEMENTATION: THE BLACK BOX OF ENFORCEMENT

The issuance of Circulars 50 and 163 is a strong indication of the Chinese government’s determination to curb the supply of corrupt payments to healthcare professionals at the national level. However, how the rules will be enforced remains to be seen. While developments in high-profile anti-bribery investigations into both domestic and international healthcare companies are widely reported in the Chinese media, to date, the NHFPC has not published the name of any company sanctioned under the revised system. This will likely be a matter of time as the central government builds the infrastructure to support the national blacklist database. In the meantime, databases established by provincial authorities under the existing blacklisting system provide examples of the application of blacklisting procedures under the 2007 rules.¹⁸

On the demand side, 2014 has seen a notable increase in rhetoric aimed at public hospitals and medical institutions suspected of corrupt activities. For example, China’s Supreme People’s Procuratorate (“SPP”), the government body charged with investigating and prosecuting criminal bribery charges, recently announced that it will continue to focus on investigating bribery cases that “jeopardize the livelihood of citizens,” including cases involving healthcare issues.¹⁹ In addition, the SPP has incentivized whistleblowers by offering Chinese citizens up to RMB100,000 (approximately US\$16,100) for tips that provide “essential evidence of misconduct.”²⁰ Despite these clear signals that Chinese regulators intend to step up enforcement efforts against bribe recipients, the government publishes no comprehensive statistics regarding anti-bribery actions brought specifically against doctors or hospitals.²¹ Accordingly, the degree to which Circular 49 will succeed in reducing demand for improper payments within the domestic healthcare industry will be difficult to measure.

IV. IMPLICATIONS FOR MULTINATIONAL HEALTHCARE COMPANIES

China is by no means alone in employing blacklisting as an anti-corruption enforcement tool. Under U.S. Federal Acquisition Regulations governing federal procurement, corporate or individual violators of the FCPA²² (or other criminal statutes) may be barred from doing business with U.S. government. Entry of a criminal or civil judgment for bribery, falsification or destruction of records, the making of false statements, or “[c]ommission of any other offense indicating a lack of business integrity or business honesty that seriously and directly affects the present responsibility of a [g]overnment contractor or subcontractor” provides grounds for debarment.²³ Indeed, the prospect of debarment from federal healthcare programs has long played a critical role in the settlement of U.S. healthcare enforcement actions, such as kickback cases, and has in recent years helped drive such settlements into the hundreds of millions – even billions – of dollars. If the implementation of Circular 50 results in more companies finding themselves caught up in China’s domestic enforcement web, the prospect of being debarred from Chinese government programs could well have a similar impact on settlement strategy, and could drive a corresponding increase in settlement numbers.

Critically, under U.S. blacklisting rules, healthcare companies that are cleared of wrongdoing by the relevant court or administrative body are free to continue contracting with the U.S. government. In China, however, becoming embroiled in an anti-bribery investigation, even one that does not result in the issuance of charges, or that ends with a victory in court, may for all practical purposes mean the end of market access.

In the last decade, U.S. enforcement agencies’ “industry sweep” of the healthcare sector has spurred multinational healthcare companies operating in China to review and revamp their compliance programs



from an FCPA perspective. As the grounds for blacklisting healthcare companies found guilty or suspected of commercial bribery violations in China have expanded and as Chinese regulators' attention has shifted to the supply side of the bribery equation, multinationals operating in this market should ensure that their internal compliance policies and practices reflect not only the latest U.S. standards, but also changes to local rules and regulations. In particular, multinationals need to ensure that they have in place policies and procedures that are reasonably designed to ensure compliance with domestic laws such as Circulars 50 and 163 and mitigate the risk of the provision of kickbacks "in any name or form" – such as donations and sponsorships linked to procurement decisions. Indeed, all pharmaceutical and medical device companies operating in China should review their sales marketing and promotional activities to confirm that, even if FCPA-compliant, they do not conflict with increasingly important local laws. The impact of these blacklisting and debarment provisions will not be fully understood until they are widely applied, as they have been in the United States. However, in the meantime, healthcare companies operating in this critical market should take note of their potentially wide-reaching impact, and undertake a proactive review of their compliance operations while the horizon is clear, rather than after the cloud of enforcement is upon them.



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¹ 15 U.S.C. §§ 78dd-1, et seq.

² See, e.g., State Administration for Industry and Commerce, *国家工商总局：重点查处医药购销商业贿赂 (Chinese Regulator Announces Campaign to Combat Commercial Bribery in the Pharmaceutical Industry)* (August 21, 2013), available at http://www.saic.gov.cn/ywdt/gsyw/zjyw/xxb/201308/t20130821_137462.html; 《国务院办公厅关于印发深化医药卫生体制改革2014年重点工作任务的通知》〈国办发〔2014〕24号〉, available at <http://www.nhfp.gov.cn/tigs/s7846/201405/c00c2f93f5b149fa85be7dd38f33dbab.shtml>.

³ 《国家卫生计生委印发〈关于建立医药购销领域商业贿赂不良记录的规定〉的通知》〈国卫法制发〔2013〕50号〉.

⁴ 《国家卫生计生委办公厅关于落实医药购销领域商业贿赂不良记录规定有关工作的通知》〈国卫办药政函〔2014〕163号〉.

⁵ 《国家卫生计生委国家中医药管理局关于印发加强医疗卫生行风建设“九不准”的通知》〈国卫办发〔2013〕49号〉.

⁶ 《关于建立医药购销领域商业贿赂不良记录的规定》(Provisions on the Establishment of Commercial Bribery Blacklists for Purchase and Distribution in the Medical Industry) 〈卫政法发〔2007〕28号〉.

⁷ *Id.* at Article 2.

⁸ Circular 50, Article 4.

⁹ *Id.* at Article 5.

¹⁰ *Id.* at Article 6.

¹¹ *Id.* at Article 7.

¹² *Id.* at Article 10.

¹³ Circular 163, Article 2.

¹⁴ *Id.*

¹⁵ *Id.* at Article 3.

¹⁶ Circular 49, Article 4.

¹⁷ *Id.* at Article 5.

¹⁸ The following jurisdictions have already established provincial blacklists: Fujian, Qinghai, Henan, Zhejiang, Chongqing, Shaanxi, Liaoning, Beijing, Guangxi, Guizhou, Jilin, Tianjin, Sichuan, and Inner Mongolia. For example, the web site for Hunan Province can be found here: <http://www.northnews.cn/2011/0218/280014.shtml>.

While the companies whose names were posted under the old blacklisting rules appear mainly to be domestic enterprises (i.e., unaffiliated with multinational companies), foreign companies or their Chinese subsidiaries have also been listed. For example, CHIC Medical Instrument Co., LTD. Fuzhou Branch (上海熙可医疗器械有限公司福州分公司) was blacklisted by the Fujian Provincial Health Department in 2008. See, *9家医药公司被列入商业贿赂不良记录黑名单 (Nine Pharmaceutical Companies Entered into Poor Record Commercial Bribery Blacklist)*, XINHUA NET (April 14, 2008), available at <http://news.51daifu.com/2008/0414/B512887DC3T14313.shtml>.

¹⁹ *高检院召开发布会通报检察机关第一季度查办职务犯罪情况 (Supreme People's Procuratorate Announces Status of Cases Involving Crimes Regarding Manipulation of Positions in the First Quarter of 2014)*, GAOJIANWANGZHIBO (May 14, 2014), available at <http://live.jcrb.com/html/2014/951.htm>.

²⁰ Yan Yiqi, *Cash Rewards Offered for Corruption Tipoffs*, CHINA DAILY (June 26, 2014), available at http://www.chinadaily.com.cn/cndy/2014-06/26/content_17615929.htm.

²¹ See note 17, *supra*. Aggregate data are available. For example, according to the SPP, the number of bribery cases prosecuted in the first quarter of 2014 that “jeopardize the livelihood of citizens” was 4,760, representing an increase of 30.2% over the first quarter of 2013.

²² 15 U.S.C. §§ 78dd-1, et seq.

²³ 48 C.F.R. §§ 9.406-2, 9.407-2.